

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application Number : 10/516,618 Confirmation No. 7130
Applicant(s) : Andreas Bergmann
Filed : December 3, 2004
Tech Cntr/AU : (unassigned)
Examiner : (unassigned)
Entitled : Methods for Diagnosing Sepsis by Determining
Anti-Asialoganglioside Antibodies

Attorney Reference : 121778-04353754
Customer Number : 43569

MAIL STOP PCT

Commissioner for Patents

P.O. Box 1450

Alexandria, Virginia 22313-1450

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §1.97

Sir:

Pursuant to 37 CFR §1.97 and 1.56, the attention of the U.S. Patent and Trademark Office is hereby directed to the following disclosures made herein, which include:

REFERENCES AND RELEVANCY

- ☒ Applicant(s) wish(es) to make of record the documents listed on the attached Form PTO-1449. Copies of the listed documents are attached, where required, as are any readily available full or partial English translations of any non-English language documents.
- ☐ Applicant(s) wish(es) to make of record the documents listed on the attached Form PTO-1449. The references cited herein were cited for consideration in the parent application, and, pursuant to 37 CFR 1.98(d), copies of the cited references can be found in the file of the parent application (U.S. Serial No. , filed).
- ☒ Applicant(s) wish(es) to make of record the documents listed on the attached Form PTO-1449. The references cited herein were cited in the International Search Report issued for the corresponding International application, and copies of the International Search Report and the cited references are attached for the Examiner's consideration.
- ☐ Applicant(s) wish(es) to make of record the documents listed on the attached Form PTO-1449. The references cited herein were cited in a communication from a foreign or international patent office in a counterpart foreign or international application(s), and copies of both the relevant communication and the cited references, where required, are attached for the Examiner's consideration.

CERTIFICATION

The undersigned certifies that, pursuant to 37 CFR §1.97(e)(1),

- ☐ each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign or international patent office in a counterpart foreign or international application not more than three months prior to the filing of this Statement.

RELATED CASES

- ☐ Identified in the attached Appendix are related applications directed to related technical subject matter. Copies of the related applications, where required, are attached for the Examiner's consideration. *The identification of the related U.S. patent applications is not to be construed as a waiver of secrecy for those applications, now or upon issuance of the present application as a patent.*

BASIS FOR CONSIDERATION

This Information Disclosure Statement is filed:

- ☒ within three months of the filing date of the application and/or before the mailing date of a first Official Action on the merits, and no fee is required [37 C.F.R. §1.97(b)].
- ☐ with the appropriate certification, and no fee is required [37 C.F.R. §1.97(e)(1)].
- ☐ after the mailing date of the first Official Action on the merits, but prior to the issuance of a Final Official Action or a Notice of Allowance, and the requisite fee, if necessary, is authorized herein for payment [37 C.F.R. §1.97(c)].
- ☐ after the mailing date of the Final Official Action or Notice of Allowance, but prior to the payment of the issue fee, the requisite certification under 37 CFR §1.97(e)(1) is made herein, and the requisite fee, if necessary, is authorized herein for payment [37 C.F.R. §1.97(d)].
- ☐ with a Request for Continued Examination (RCE), and no fee is required [37 C.F.R. §1.97(b)(4)].

FEE AUTHORIZATION

- ☒ Authorization is hereby given to charge any deficient fee(s) under 37 CFR §1.16 and §1.17 as necessary to ensure the consideration of this disclosure, or to credit any fee overpayments, to Deposit Account No. 503-121.
- ☐ Authorization is hereby given to charge the requisite fee of \$180 (Fee Code 1806) for submission of this Information Disclosure Statement to Deposit Account No. 503-121.

It is respectfully requested that this information be expressly considered during the prosecution of this application, and that the reference(s) be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

The Examiner is further respectfully requested to return of a copy of the enclosed Form PTO-1449 with the Examiner's initials in the left column.

The examination and allowance of this Application is respectfully requested.

Respectfully Submitted,

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Date: May 25, 2005
Attachment(s): PTO Form 1449
International Search Report
Cited References

**INFORMATION DISCLOSURE STATEMENT
BY APPLICANT**

Attorney Reference: 121778-04353754

Applicant: Andreas Bergmann

Application Serial No. 10/516,618

Filing Date: December 3, 2004

Date: May 25, 2005

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Examiner: (unassigned) Group Art Unit: (unassigned)

U.S. PATENT DOCUMENTS

Examiner's Initials*	Document Number	Date MM/YYYY	Name (Family Name of First Inventor)	Class	Sub Class	Filing Date (if appropriate)
AR	5,639,617	06/1997	Bouhoun			
BR	6,756,483	06/2004	Bergmann et al.			
CR						

FOREIGN PATENT DOCUMENTS

		Document Number	Date MM/YYYY	Country		Translation Readily Available		English Abstract	
						Enclosed	No	Enclosed	No
	DR	WO 00/22439	04/2000	International					
	ER	WO 02/18950	03/2002	International					
	FR	WO 02/17770	03/2002	International					
	GR	WO 99/40433	08/1999	International					
	HR	DE 42 27 454 C1	02/1994	Germany	* see US equivalent above		X		X
	IR	DE 198 47 690 A1	04/2000	Germany	* see US equivalent above		X		X
	JR	EP 0 656 121 B1	03/1998	Europe					
	KR								

OTHER (Including in this order Author, Title, Periodical Name, Date, Pertinent Pages, etc.)

LR	Meléndez-Vásquez, C. et al., "Immunological investigation of chronic inflammatory demyelinating polyradiculoneuropathy," <i>Journal of Neuroimmunology</i> , vol. 73, 3/1997, pp. 124-134.
MR	Reinhart, K. et al., "Sepsis und septischer Schock," <i>Intensivmedizin</i> , Georg Thieme Verlag, Stuttgart (2001) pp. 756-760.
NR	Beishuizen, A. et al., "Endogenous Mediators in Sepsis and Septic Shock," <i>Advances in Clinical Chemistry</i> , vol. 33, 1998, pp. 55-131.
OR	Gabay, C. et al., "Acute-Phase Proteins and Other Systemic Responses to Inflammation," <i>The New England Journal of Medicine</i> , vol. 340, no. 6, 2/11/1999, pp. 448-454
PR	Assicot, M. et al., "High serum procalcitonin concentrations in patients with sepsis and infection," <i>The Lancet</i> , vol. 341, 2/27/1993, pp. 515-518
QR	Karzai, W. et al., "Procalcitonin – A New Indicator of the Systemic Response to Severe Infections," <i>Infection</i> , vol. 25, no. 6, 11/1997, pp. 329-334.
RR	Oczenski, W. et al., "Procalcitonin: a new parameter for the diagnosis of bacterial infection in the peri-operative period," <i>European Journal of Anaesthesiology</i> , vol. 15, 1998, pp. 202-209.
SR	Redl, H. et al., "Procalcitonin release patterns in a baboon model of trauma and sepsis: Relationship to cytokines and neopterin," <i>Crit Care Med</i> , vol. 28, no. 11, 2000, pp. 3659-3663.
TR	Redl, H. and G. Schlag, "Non-Human Primate Models of Sepsis," <i>Sepsis</i> , vol. 2, 1998, pp. 243-253.
UR	Panacek, E.A., "Anti-TNF strategies," <i>Journal für Anästhesie und Intensivbehandlung</i> , 2/2001, pp. 4-5.
VR	Calandra, T. et al., "Protection from septic shock by neutralization of macrophage migration inhibitory factor," <i>Nature Medicine</i> , vol. 6, no. 2, 2/2000, pp. 164-170.
WR	Garber, K., "Protein C may be sepsis solution," <i>Nature Biotechnology</i> , vol. 18, 9/2000, pp. 917-918.

Examiner

Date Considered:

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

**INFORMATION DISCLOSURE STATEMENT
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Attorney Reference: 121778-04353754

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Page 2 of 2

Examiner: (unassigned)

Group Art Unit: (unassigned)

U.S. PATENT DOCUMENTS

Examiner's Initials*	Document Number	Date MM/YYYY	Name (Family Name of First Inventor)	Class	Sub Class	Filing Date (if appropriate)
	XR					
	YR					

FOREIGN PATENT DOCUMENTS

		Document Number	Date MM/YYYY	Country			Available		Abstract	
							Enclosed	No	Enclosed	No
	ZR									
	AAR									

OTHER (Including in this order Author, Title, Periodical Name, Date, Pertinent Pages, etc.)

	BBR	Weller, M. et al., "Ganglioside antibodies: a lack of diagnostic specificity and clinical utility?," <i>Journal of Neurology</i> , vol. 239, 1992, pp. 455-459.
	CCR	Bech, E. et al., "ELISA - Type Titertray Assay of IgM Anti-GM1 Autoantibodies," <i>Clinical Chemistry</i> , vol. 40, no. 7, 1994, pp. 1331-1334.
	DDR	Pestronk, A. et al., "Multifocal motor neuropathy: Serum IgM anti-GM1 ganglioside antibodies in most patients detected using covalent linkage of GM1 to ELISA plates," <i>Neurology</i> , 11/1997, pp. 1289-1292.
	EER	Ravindranath, M. et al., "Factors affecting the fine specificity and sensitivity of serum antiganglioside antibodies in ELISA," <i>Journal of Immunological Methods</i> , vol. 169, 1994, pp. 257-272.
	FFR	Alaedini, A. et al., "Detection of Anti-GM1 Ganglioside Antibodies in Patients with Neuropathy by a Novel Latex Agglutination Assay," <i>Journal of Immunoassay</i> , vol. 21, no. 4, 2000, pp.377-386.
	GGR	Alaedini, A. et al., "Ganglioside Agglutination Immunoassay for Rapid Detection of Autoantibodies in Immune-Mediated Neuropathy," <i>Journal of Clinical Laboratory Analysis</i> , vol. 15, 2001, pp. 96-99.
	HHR	Pross, H. et al., "Role of Natural Killer Cells in Cancer," <i>Nat Immun</i> , vol. 12, 1993, pp. 279-292.
	IIR	Lanier, L. et al., "Arousal and inhibition of human NK cells," <i>Immunological Reviews</i> , vol. 155, 1997, pp. 145-154.
	JJR	Fujii, Y. et al., "IgG Antibodies to AsialoGM1 Are More Sensitive than IgM Antibodies to Kill <i>in vivo</i> Natural Killer Cells and Prematured Cytotoxic T Lymphocytes of Mouse Spleen," <i>Microbiol. Immunol.</i> , vol. 34, no. 6, 1990, pp. 533-542.
	KKR	Saijo, N. et al., "Analysis of Metastatic Spread and Growth of Tumor Cells in Mice with Depressed Natural Killer Activity by Anti-asialo GM1 Antibody or Anticancer Agents," <i>Cancer Research Clinical Oncology</i> , vol. 107, 1984, pp. 157-163.
	LLR	Habu, S. et al., "Role of Natural Killer Cells against Tumor Growth in Nude Mice - A Brief Review," <i>J Exp Clin Med</i> , vol. 8, no. 5, 6, 1983, pp. 465-168.
	MMR	Lanier, L., "NK Cell Receptors," <i>Annu. Rev. Immunol.</i> , vol. 16, 1998, pp. 359-393.
	NNR	Whiteside, T. et al., "The role of natural killer cells in immune surveillance of cancer," <i>Current Opinion in Immunology</i> , vol. 7, 1995, pp. 704-710.
	OOR	Timonen, T. et al., "Natural killer cell-target cell interactions," <i>Current Opinion in Cell Biology</i> , vol. 9, 1997, pp. 667-673.
	PPR	International Search Report from PCT/EP03/03449 mailed 6/25/03

Examiner

Date Considered:

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